Initial REMS Approval: 12/2010
Most Recent Modification: 09/2013

NDA 21-463
FORTESTA® (testosterone) gel CIII

Class of Drug: Androgen

Endo Pharmaceuticals Inc. (Endo)
1400 Atwater Drive, Malvern, PA 19355
Phone: (484) 216-0000; Fax: (610) 884-5834

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of this REMS is to inform patients about the serious risks associated with the use of FORTESTA (testosterone) gel.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each FORTESTA (testosterone) gel prescription in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS and is appended.

B. Timetable for Submission of Assessments

Endo will submit REMS assessments to FDA 18 months, 3 years and 7 years from the date of the initial approval (12/2010) of the FORTESTA REMS. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Endo will submit each assessment so that it will be received by FDA on or before the due date.

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CHRISTINE P NGUYEN
09/11/2013